AUG 1 3 2002

K022354

UltraGuide Ltd.

510(k) Summary

CTG 2000sa

I. Submitter Information

A. Name: UltraGuide Ltd.

B. Address: Yoqne'am, New Industrial Park,
7b Hayezira st., Israel
UltraGuide P.O.B 570
Yokneam Illit 20692

C. Contact Person: Dr. George Myers, 201-727-1703, Fax 201-727-1708

D. Date of preparation: July 3, 2002

II. Device Data

A. Trade Name: CTG 2000sa

B. Common Name: Visualization Enhancement System of Interventional Needles under imaging by computed tomography

C. Classification Name: System, X-Ray, Tomography, Computed

III. Legally-marketed predicate devices.

A. CT- Guide 1010, K002258

IV. Description

The CTG 2000sa provides visual enhancement of the interventional needle by overlaying the image of the insertion device and its predicted future path on the CT image of the internal organs, all displayed on the monitor of a personal computer.

V. Intended Use

The CTG 2000sa system is a stereotactic accessory for Computed Tomography (CT) systems. It displays the simulated image of a rigid interventional instrument, such as a

biopsy needle or an aspiration needle, on a computer monitor screen that also shows the CT image of the target organs and the projected future path of the interventional instrument, compensating for respiratory movements of the patient.

The device is intended to be used in clinical applications and for anatomical structures where computed tomography is currently used for visualizing such procedures.

VI. Technological characteristics

The device uses magnetic transmitters and receivers, sold under the trade name "PC Birds," to determine the location and orientation of the interventional needle. These devices have been used on medical devices cleared by the FDA. The positions and orientations of the interventional device, and the video of the CT image, are transmitted to a Personal Computer, which makes the necessary calculations to provide the overlay of the video image and the interventional device.

VII. Testing

A. Non-clinical tests

The CTG 2000sa has undergone extensive bench tests for electrical safety and electromagnetic compatibility. The major components (the computer, ultrasound system, and PC Birds) are all commercial devices with published environmental and physical specifications.

Accuracy tests were done in phantoms.

B. Clinical Test

Since this system uses the same technology as the predicate device, a clinical test is not necessary.

VIII. Conclusion

The tests show that the UltraGuide CTG 2000sa is equivalent to the predicate devices in safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2002

UltraGuide, Ltd.
% Dr. George Myers
Official Correspondent
Medsys, Inc.
377 Route 17 South
HASBROUCK HEIGHTS NJ 07604

Re: K022354
Trade/Device Name: UltraGuide CTG 2000sa
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: July 10, 2002
Received: July 19, 2002

Dear Dr. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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510(k) Number (if known): K022354

Device Name: CTG 2000sa

Indications for Use:

The CTG 2000sa system is a stereotactic accessory for Computed Tomography (CT) systems. It displays the simulated image of a rigid interventional instrument, such as a biopsy needle or an aspiration needle, on a computer monitor screen that also shows the CT image of the target organs and the projected future path of the interventional instrument, compensating for respiratory movements of the patient.

The device is intended to be used in clinical applications and for anatomical structures where computed tomography is currently used for visualizing such procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use ✓

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022354